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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/090,038 | 02/27/2002 | James R. Komorowski | NUTRI.023A | 6775 |

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KNOBBE MARTENS OLSON & BEAR LLP
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EXAMINER

CHOI, FRANK I

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1616

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

10/090,038

Applicant(s)

KOMOROWSKI ET AL.

Examin r

Frank I Choi

Art Unit

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-- The MAILING DATE of this communication appears n the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

Examiner notes that document number 18 listed US Pat. 6,014,846, with Cochran listed as the inventor and a publication date of 4/11/2000. A review of the patent reference, which accompanied the IDS, reveals that the inventor in said Patent is Sono et al., the title of the Patent is "Multi-Windo Sash and Batten Attachment Structure", and the publication date is 1/18/2000. As said reference does not appear to have any relevance to the claimed invention, Examiner believes that the patent number listed is incorrect. Examiner believes that the correct patent number is US Pat. 6,048,846 issued to Cochran on 4/11/2000. Examiner has obtained a copy, considered and placed the same in the file and corrected the patent number in the PTO-1449 by crossing-out "6,014,846" and inserting "6,048,846". Examiner respectfully requests that Applicant advise as to the correctness of said action in the response to the Office Action herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 21,22 are rejected under 35 U.S.C. 102(b) as being anticipated by McCarty (US Pat. 5,789,401) or McCarty (US Pat. 5,929,066).

McCarty (US Pat. 5,789,401) expressly discloses a pharmaceutical composition containing chromic tripicolinate and biotin wherein the ratio of the chromic tripicolinate to biotin is between about 100:1 and 5:1 (w/w) (Column 2, lines 42-45).

McCarty (US Pat. 5,929,066) expressly discloses a pharmaceutical composition containing chromic tripicolinate and biotin wherein the ratio of the chromic tripicolinate to biotin is between about 2:1 and 1:200 (w/w) (Column 2, lines 48-54).

Claims 1-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCarty (US Pat. 5,789,401) or McCarty (US Pat. 5,929,066), each in view of de la Harpe et al. (US Pat. 5,948,772) and Brand-Miller.

McCarty (US Pat. 5,789,401) teaches a pharmaceutical composition containing chromic tripicolinate and biotin wherein the ratio of the chromic tripicolinate to biotin is between about 100:1 and 5:1 (w/w) (Column 2, lines 42-45). It is taught that the for reducing hyperglycemia and stabilizing the level of serum glucose between about 1000 and 10000 micrograms of chromium tripicolinate in combination with between about 1 mg and 200 mg per day of biotin in a pharmaceutically acceptable carrier and that the same may be orally or parenterally administered (Column 2, lines 23-41). It is taught that for oral administration that the composition may be provided as an aqueous or oil suspension, dispersible powder or granule, emulsion, syrup or elixir (Column 3, lines 6-9).

McCarty (US Pat. 5,929,066) teach a pharmaceutical composition containing chromic tripicolinate and biotin wherein the ratio of the chromic tripicolinate to biotin is between about

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2:1 and 1:200 (w/w) (Column 2, lines 48-54). It is taught that the for reducing hyperglycemia and stabilizing the level of serum glucose between about 50 and 1000 micrograms of chromium tripicolinate in combination with between about 25 micrograms and 200 mg per day of biotin in a pharmaceutically acceptable carrier and that the same may be orally or parenterally administered (Column 2, lines 28-47).). It is taught that for oral administration that the composition may be provided as an aqueous or oil suspension, dispersible powder or granule, emulsion, syrup or elixir (Column 3, lines 13-16).

de la Harpe et al. teach that chromium supplements, such as chromium tripicolinate, reduce hyperglycemia, stabilize serum glucose and control blood serum lipid levels, including the lowering of undesirably high blood serum LDL-cholesterol levels and the raising of blood serum HDL-cholesterol levels (Column 2, lines 30-38). It is taught that addition of nicotinic acid and/or picolinic acid facilitates the absorption of other ingested chromium in the human diet (Column 5, lines 1-15). It is taught that chromic polynicotinate has the same uses as chromium tripicolinate (Column 2, lines 38-41, Column 5, lines 9-16). It is taught that for oral administration, the composition may be incorporated into a aqueous or oil suspension, dispersible powder or granule, emulsion, syrup or elixir or the components may also be administered separately (Column 5, lines 30-37).

Jensen teaches that chromium nicotinate is effective in reducing triglycerides Column 10, lines 35-68, Column 11, lines 1-56). It is taught that compositions containing the same can be administered orally, as liquid solutions or suspensions or powders and that the same can be administered independently or as a food supplement, including incorporating the same into a

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food or drink, or the same can be administered parenterally (Column 7, lines 13-29, Column 14, lines 3-6).

Brand-Miller teaches that glycemic index (GI) a concept that ranks foods on the basis of their acute glycemic impact (Pg. 747S). It is taught that unlike high-fiber diets, low GI diets are "user friendly" (Pg. 750S). It is taught that measurable clinical gains are associated with diets in which that GI has been reduce by at least 11 units, by exchanging 50% of the carbohydrate from high- to low-GI food (Pg. 750S).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a method of treating dyslipidemia by administering, a method of reducing the glycemic index of food by adding to said food, or a food having a reduced glycemic index by adding, the combination of a chromium complex and biotin. However, the prior art amply suggests the same as it is known in the art that the combination of chromium tripicolinate and biotin is effective in reducing hyperglycemia and stabilizing the level of serum glucose, that chromium complexes such as chromium tripicolinate and chromium nicotinate are effective in reducing serum lipid levels and may be administered separately or incorporated into food, and that a diet of low glycemic index foods are effective in treating diabetes. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use the combination of chromium complex and biotin with the expectation that the same would be effective in reducing high LDL and triglyceride levels, raising low HDL levels and that since the combination of chromium complex and biotin reduces hyperglycemia and stabilizes the level of serum glucose the incorporation of the same into foods would reduce the acute glycemic response to said food resulting in a lower GI for said food.

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Conclusion


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

May 16, 2003


JOHN PAK
PRIMARY EXAMINER
GROUP 1600

